IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

PLAINTIFF'S RESPONSE TO DEFENDANTS' OBJECTIONS TO THE PROPOSED STATEMENT OF PLAINTIFF'S EXPERT SANDER GREENLAND, PH.D.

Plaintiff Ruth Smith, as the Widow for the use and benefit of herself and the next of kin of Richard Smith, deceased, by and through her attorneys, hereby submits Plaintiff's Response to Defendants' Objections to the Proposed Statement of Plaintiff's Expert Sander Greenland, Ph.D.

Testimony	Objection	Response
¶4.a. It is my opinion that the data that Pfizer provided to the FDA as part of its response on suicidality and Neurontin did not show that Neurontin does not cause suicidal behavior and ideation (suicidality).	• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702) • Improperly attempts to shift the burden of proof to defendant • Not helpful to trier of fact (FRE 702)	See expert report of Sander Greenland dated 10/19/2007 pp. 6-15. Defendants claim that their submissions to the FDA prove that Neurontin does not cause suicidal behavior.

Testimony	Objection	Response
¶4.d. Pfizer's expert Dr. Robert Gibbons' opinions on the FDA alert are deceptive and are biased	• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)	Dr. Greenland extensively reviewed Dr. Gibbons' opinions in the following Greenland Reports: May 2, 2008 July 22, 2008 May 31, 2009 March 19, 2010 Dr. Greenland's opinion is based upon an exhaustive review of Dr. Gibbons work and goes to the weight of the opinions presented by Dr. Gibbons.
¶4.e. Dr. Gibbons' expert reports are so flawed and biased that they have no scientific validity and should be dismissed. In particular, they present conclusions that cannot be supported by the data they discuss and which are in fact absent from the publications discussing the data, showing that those conclusions have been tailored for the defendant rather than reached by any sound scientific methodology from the data presented.	• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403) • Contrary to prior rulings by Judge Saris in the MDL that Dr Gibbons' opinions concerning the FDA meta-analysis and bipolar study are based on reliable methodology and therefore admissible under FRE 702 and *Daubert*	See above. on 4.d Dr. Greenland is a peer reviewer for statistical journals and is qualified to render these opinions. Despite Judge Saris' rulings, some of which are still pending, Dr. Greenland is allowed to attack the weight of the opinions offered by Dr. Gibbons.

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¶4.f. Dr. Gibbons' papers suffer from the usual methodologic problems associated with data base studies of this type and cannot be taken as showing that Neurontin prevents or causes suicidality.	• Foundation, insufficient bases for opinion (FRE 703)	See Dr. Greenland's report dated May 31, 2009 generally and specifically pp. 4-6.
¶6. The FDA found that these drugs were associated with an 80% increase in risk in randomized placebo-controlled trials. This means that trial subjects who were given one of these drugs were twice as likely to show suicidal behavior or ideation as those who were given a placebo (an inert pill) instead.	• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)	These are the findings of the FDA. Defendants are free to cross examine Dr. Greenland. These findings form the basis of the FDA alert and labeling changes.
¶6. On the panel were three scientists who are experts in statistics and who had no criticisms of the FDA's work.	• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)	This is an accurate statement based upon the FDA Advisory Committee hearing. Defendants are free to cross examine Dr. Greenland. Defendants use the results of the Advisory Committee that did not recommend a black box in their witness statements. Other occurrences at the meeting are just as probative and are not prejudicial.

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¶6. Pfizer had an opportunity to present their opinion that Neurontin does not cause suicidal behavior, but the FDA reviewed what Pfizer had to say and rejected their opinions.	• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403) • Rule of completeness (FRE 106)	This is an accurate statement based upon the FDA Advisory Committee hearing. Defendants are free to cross examine Dr. Greenland. The FDA specifically reviewed Pfizer's briefing materials and data and disagreed with Pfizer's opinions. FDA scientists presented as much at the meeting.
All of ¶7	• Not helpful to trier of fact (FRE 702)	The court has denied Defendants' *motion in limine* on this topic

Testimony	Objection	Response
¶7. The rate of suicidal acts among gabapentin users was 1.42 times (42%) higher than that in topirimate users (95% confidence interval 1.11 to 1.80). In Figure 2 of the 2008 FDA report, topirimate patients showed 2.53 times the suicidality risk of placebo patients in clinical trials. Thus, relative to a placebo, the excess of risk seen for gabapentin relative to topirimate would correspond to 1.42 times 2.53, or a 3.6-fold increase in risk.	• His formula has never been peer-reviewed, tested, or accepted in any scientific community. Never been used outside this litigation. • Formula shows opposite (i.e., protective) effect when used with Olesen data. • Patorno study is non-randomized observational study • FDA's own meta-analysis of the gabapentin randomized placebo-controlled clinical trial data (which Dr. Greenland relies upon) put odds ratio at 1.57, with a confidence interval that crosses 1.0 • Admits that, beyond the Patorno study, "I wouldn't have any certainty about any of the differences based on other data." • Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702) • Not helpful to trier of fact (FRE 702) • Unfairly prejudicial statement seeks to mislead the jury by interposing discussion of recent "exploratory" non-randomized and un-controlled survey with the FDA	Dr. Greenland's multiplication of the two facts follows from standard statistical methods. Defendants' argument is essentially that Dr. Greenland's methods are unreliable because nobody ever did the math in this particular case. It is well established that relative risks can be multiplied. Defendants arguments about what the papers and FDA analyses show and dont show are proper cross examination topics. Defendants arguments go to the weight of the testimony and not its admissibility. Defendants are free to cross examine.

Testimony	Objection	Response
¶8. Dr. Robert Gibbons opinions on the FDA alert are so biased that they are unreliable. He makes statistical statements that are not based on sound methodology. He also makes serious statistical errors, every one of which is in favor of Pfizer; yet the average reader would have no way to recognize these errors.	• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403) • Contrary to prior rulings by Judge Saris in the MDL that Dr Gibbons' opinions concerning the FDA meta-analysis and bipolar study are based on reliable methodology and therefore admissible under FRE 702 and *Daubert*	See above. on 4.d Dr. Greenland is a peer reviewer for statistical journals and is qualified to render these opinions. Despite Judge Saris' rulings, some of which are still pending, Dr. Greenland is allowed to attack the weight of the opinions offered by Dr. Gibbons.
¶9. Dr. Gibbons' opinion that his studies establish that gabapentin is protective of suicide or at least has no effect appears to be tailored exclusively for this litigation rather than founded on any sound scientific inference method	• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403) • Contrary to prior rulings by Judge Saris in the MDL that Dr Gibbons' opinions concerning the FDA meta-analysis and bipolar study are based on reliable methodology and therefore admissible under FRE 702 and *Daubert*	See above. on 4.d Dr. Greenland is a peer reviewer for statistical journals and is qualified to render these opinions. Despite Judge Saris' rulings, some of which are still pending, Dr. Greenland is allowed to attack the weight of the opinions offered by Dr. Gibbons.

Dated: May 13, 2010

Respectfully submitted,

THE LANIER LAW FIRM, P.L.L.C.

By: **/s/ W. Mark Lanier**

W. Mark Lanier, Esq.
Dara G. Hegar, Esq.
Ken S. Soh, Esq.
Maura Kolb, Esq.
Robert Leone, Esq.
126 East 56th Street, 6th Floor
New York, NY 10022

- and -

FINKELSTEIN & PARTNERS, LLP

By: **/s/ Andrew G. Finkelstein**

Andrew G. Finkelstein, Esq.
Kenneth B. Fromson, Esq.
1279 Route 300, P.O. Box 1111
Newburgh, NY 12551

- and -

BARRETT & ASSOCIATES, P.A.

By: **/s/ Charles F. Barrett**

Charles F. Barrett, Esq.
BPR # 020627
6518 Highway 100, Suite 210
Nashville, TN 37205

Attorneys for Plaintiff Ruth Smith

CERTIFICATE OF SERVICE

I hereby certify that on this the 13th day of May, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

Aubrey B. Harwell, Jr., Esq.
W. David Bridgers, Esq.
Gerald D. Neenan, Esq.
Robert A. Peal, Esq.
Neal & Harwell, PLC
2000 One Nashville Place
150 Fourth Avenue, North
Nashville, TN 37219

Prince C. Chambliss, Jr., Esq.
Evans & Petree, PC
1000 Ridgeway Loop Road, Suite 200
Memphis, TN 38120

Mark S. Cheffo, Esq.
Catherine B. Stevens, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
Four Times Square
New York, NY 10036

Andrew Howell Myers, Esq.
James Ernest Hooper, Esq.
Stephen Ernest Oertle, Esq.
Wheeler Trigg O'Donnell LLP
1801 California Street, Suite 3600
Denver, CO 80202-2617

Faith E. Gay, Esq.
Quinn, Emanuel, Urquhart, Oliver & Hedges, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010

/s/ Andrew G. Finkelstein
Andrew G. Finkelstein